IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robbins et al.

Serial No.: 09/844,915 Examiner: Not yet assigned

Filing Date: April 27, 2001 Group Art: 1633

Title of Invention: THE USE OF TOLEROGENIC DENDRITIC CELLS FOR ENHANCING THE TOLEROGENICITY IN A HOST AND METHODS FOR MAKING THE SAME

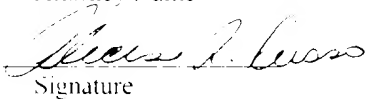
INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

December 19, 2001
Date of Deposit

Alicia A. Russo
Attorney Name

46,192
PTO Registration No.


Signature

December 19, 2001
Date of Signature

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with 37 C.F.R. § 1.56, Applicants respectfully request that the references relating to the above-mentioned application filed concurrently herewith listed herein in reverse chronological order be made of record in the U.S. Patent and Trademark Office.

1 Hirano *et al.*, "Graft hyporeactivity induced by immature donor-derived

dendritic cells," *Transplant Proc.* 32:260-264 (2000)

2. United States Patent No. 5,871,728 by Thomson *et al.*, filed March 31, 1995, issued February 16, 1999

3. Gao *et al.*, "CD40-deficient dendritic cells producing interleukin-10, but not interleukin-12, induce T-cell hyporesponsiveness in vitro and prevent acute allograft rejection." *Immunology* 98 :159-170 (1999).

4. Lee *et al.*, " Cyclosporine A inhibits the expression of costimulatory molecules on in vitro-generated dendritic cells: association with reduced nuclear translocation of nuclear factor kappa B,"*Transplantation* 68:1255-1263 (1999).

5. Lu *et al.*, "Genetic engineering of dendritic cells to express immunosuppressive molecules (viral IL-10, TGF-beta, and CTLA4Ig)," *J. Leukoc. Biol.* 66:293-296 (1999).

6. Lu *et al.*, " Adenoviral delivery of CTLA4Ig into myeloid dendritic cells promotes their in vitro tolerogenicity and survival in allogeneic recipients,"*Gene Ther.* 6:554-563 (1999).

7. Ranieri *et al.*, " Dendritic cells transduced with an adenovirus vector encoding Epstein-Barr virus latent membrane protein 2B: a new modality for vaccination,"*J. Virol.* 73:10416-10425 (1999).

8. Rea *et al.*, "Adenoviruses activate human dendritic cells without polarization toward a T-helper type 1-inducing subset,"*J. Virol.* 73:10245-10253 (1999).

9. Thomson and Lu, "Dendritic cells as regulators of immune reactivity:

implications for transplantation," *Transplantation* 68:1-8 (1999).

10. Tuting *et al.*,"Dendritic cell-based genetic immunization in mice with a recombinant adenovirus encoding murine TRP2 induces effective anti-melanoma immunity," *J. Gene Med.* 1:400-406 (1999).

11. Banchereau and Steinman, "Dendritic cells and the control of immunity," *Nature* 392:245-252 (1998).

12. Khanna *et al.*, " Donor bone marrow potentiates the effect of tacrolimus on nonvascularized heart allograft survival: association with microchimerism and growth of donor dendritic cell progenitors from recipient bone marrow," *Transplantation* 65:479-485 (1998).

13. Lee *et al.*,"Phenotype, function, and in vivo migration and survival of allogeneic dendritic cell progenitors genetically engineered to express TGF-beta,"*Transplantation* 66:1810-1817 (1998).

14. Lu *et al. Journal of Leukocyte Biology* Supplement 2 Abstract#B52 (1998).

15. Rescigno *et al.*,"Dendritic cell survival and maturation are regulated by different signaling pathways," *J. Exp. Med.* 188:2175-2180 (1998).

16. Lu *et al.*, "Blockade of the CD40-CD40 ligand pathway potentiates the capacity of donor-derived dendritic cell progenitors to induce long-term cardiac allograft survival," *Transplantation* 64:1808-1815 (1997).

17. Fu *et al.*, "Costimulatory molecule-deficient dendritic cell progenitors

induce T cell hyporesponsiveness in vitro and prolong the survival of vascularized cardiac allografts." *Transplant Proc.* 29:1310 (1997).

18. Fu *et al.*, " Costimulatory molecule-deficient dendritic cell progenitors (MHC class II+, CD80dim, CD86-) prolong cardiac allograft survival in nonimmunosuppressed recipients," *Transplantation* 62:659-665 (1996).

19. Lu *et al.*, "Induction of nitric oxide synthase in mouse dendritic cells by IFN-gamma, endotoxin, and interaction with allogeneic T cells: nitric oxide production is associated with dendritic cell apoptosis," *J. Immunol.* 157:3577-3586 (1996).

20 Lu *et al.*," Bone marrow-derived dendritic cell progenitors (NLDC 145+, MHC class II+, B7-1dim, B7-2-) induce alloantigen-specific hyporesponsiveness in murine T lymphocytes," *Transplantation* 60:1539-1545 (1995).

21. Rastellini *et al.*," Granulocyte/macrophage colony-stimulating factor-stimulated hepatic dendritic cell progenitors prolong pancreatic islet allograft survival,"*Transplantation* 60:1366-1370 (1995).

22. Andrews and Faller, " A rapid micropreparation technique for extraction of DNA-binding proteins from limiting numbers of mammalian cells,"*Nucleic Acids Res.* 19:2499 (1991).

23. Jolly, D., "Viral vector systems for gene therapy," *Cancer Gene Therapy*, 1:51-64. (1994).

24. Starzl *et al.*,"The biological basis of and strategies for clinical xenotransplantation," *Immunological Reviews* 141:213 (1994).

25. Woo *et al.*, "Isolation, phenotype, and allostimulatory activity of mouse liver dendritic cells," *Transplantation* 58:848 (1994).

26. Berkner, K.L., "Expression of heterologous sequences in adenoviral vectors," *Curr. Top. Micro Immunol*, 158:39-66. (1992).

27. Inaba *et al.*,"Generation of large numbers of dendritic cells from mouse bone marrow cultures supplemented with granulocyte/macrophage colony-stimulating factor," *J. Exp. Med.* 176:1693-1702 (1992).

28. Horwitz, M.S., "Adenoviridae and Their Replication," in *Virology*, 2nd edition, Fields *et al.*, eds., Raven Press, New York, 1990

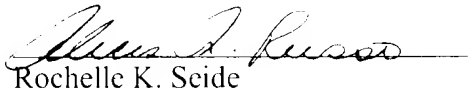
29. Billiar *et al.*,"An L-arginine-dependent mechanism mediates Kupffer cell inhibition of hepatocyte protein synthesis in vitro," *J. Exp. Med.* 169:1467-1472 (1989).

The referenced citations are listed in the accompanying PTO Form 1449 and copies of the references are provided. Identification of the above-listed references is not to be construed as an admission of the Applicant or the attorneys of the Applicant that such references are available as "prior art" against the subject application.

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the above-mentioned application.

Applicants believe that there is no fee required for this submission. However, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4377. A duplicate of this sheet is enclosed.

Respectfully submitted,



Rochelle K. Seide
Patent Office Reg. No. 32,300

Alicia A. Russo
Patent Office Reg. No. 46,192

Attorneys for Applicants
(212) 408-2627